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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|----------------------------------------------------------------|-----------------------|----------------------|---------------------|------------------|--|
| 10/535,527 | 05/26/2006 | Aravinda Thagalingam | 16973-2 | 9351 | |
| Woodard Emha | 7590 06/25/200 rdt | EXAMINER | | | |
| Bank One Cente | | DELLA, JAYMI E | | | |
| 111 Monument Circle, Suite 3700 Indianapolis, IN 46204-5137 | | ART UNIT | PAPER NUMBER | | |
| • | - | | | 4137 | |
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| | | | MAIL DATE | DELIVERY MODE | |
| | | | 06/25/2009 | PAPER | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | Application No. | Applicant(s) | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------|--|--|--|
| | 10/535,527 | THAGALINGAM ET AL. | | | |
| Office Action Summary | Examiner | Art Unit | | | |
| | JAYMI DELLA | 4137 | | | |
| The MAILING DATE of this communication app | pears on the cover sheet with the c | correspondence address | | | |
| Period for Reply | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPL' WHICHEVER IS LONGER, FROM THE MAILING D. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period of Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from , cause the application to become ABANDONE | N. nely filed the mailing date of this communication. D (35 U.S.C. § 133). | | | |
| Status | | | | | |
| 1)⊠ Responsive to communication(s) filed on <u>26 M</u> | lav 2006 | | | | |
| • • • • • • • • • • • • • • • • • • • • | action is non-final. | | | | |
| | | | | | |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | |
| 4)⊠ Claim(s) <u>1-88</u> is/are pending in the application. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | |
| 5) Claim(s) is/are allowed. | | | | | |
| 6) Claim(s) is/are rejected. | | | | | |
| 7) Claim(s) is/are objected to. | | | | | |
| 8) Claim(s) <u>1-88</u> are subject to restriction and/or | election requirement. | | | | |
| Application Papers | | | | | |
| 9)☐ The specification is objected to by the Examine | er. | | | | |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner. | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | |
| 11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). | | | | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | | |
| 1. Certified copies of the priority documents have been received. | | | | | |
| 2. Certified copies of the priority documents have been received in Application No | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | |
| | | | | | |
| Attachment(s) | - | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4) ☐ Interview Summary Paper No(s)/Mail Da | | | | |
| 3) Information Disclosure Statement(s) (PTO/SB/08) | 5) Notice of Informal F | | | | |
| Paper No(s)/Mail Date | 6) Other: | | | | |

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DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, 26-40, drawn to a surgical device for treating tissue with a helical fixing member.

Group II, claim(s) 13-25, drawn to surgical methods for treating tissue with a catheter by deploying a helical fastening needle.

Group III, claim(s) 41-57, drawn to surgical methods for treating tissue with an outer and inner elongate member by deploying a helical fastening needle.

Group IV, **claim(s) 58-74**, drawn to surgical device for treating tissue with a shape memory alloy wire having a helical shape at one end.

Group V, claim(s), 75-88, drawn to surgical methods for treating tissue using a shape memory alloy wire having a helical shape at one end.

2. The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the common technical feature between Groups I, II, III, IV, and V is a helical member. This element cannot be a special technical feature under PCT Rule 13.2 because the element is

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shown in the prior art. Altman et al. (U.S. Patent No. 6,358,247) disclose a helical coil (102) in a surgical device that treats tissue. Therefore, this feature cannot be a special technical feature under PCT Rule 13.2 because it fails to provide contribution to the prior art.

3. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

Set I:

Species A, a lumen configuration with the smaller lumen inside the larger lumen as illustrated in Fig. 10.

Species B, a lumen configuration with the smaller lumen outside the larger lumen as illustrated in Fig. 11

Species C, a lumen configuration where the smaller lumen is within a thicker wall portion of the larger lumen as illustrated in Fig. 12.

Set III:

Species A, deployment of the helical fastening member from the large lumen as specified on Pg. 26, Lines 14-15.

Species B, deployment of the helical fastening member from the small lumen as specified on Pg. 26, Lines 14-15.

Set IV:

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Species A, a needle tip with a closed terminal end as illustrated in Fig.

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3A-3D.

Species B, a needle tip with an open terminal end as illustrated in Fig. 3E.

4. Applicant is required, in reply to this action, to elect a single species for each set

to which the claims shall be restricted if no generic claim is finally held to be allowable.

The reply must also identify the claims readable on the elected species, including any

claims subsequently added. An argument that a claim is allowable or that all claims are

generic is considered non-responsive unless accompanied by an election.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration

of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the

elected species. MPEP § 809.02(a).

6. The claims are deemed to correspond to the species listed above in the following

manner:

Set I:

Species A: 1-88

Species B: 1-88

Set II:

Species A: 1-18, 20-88

Species B: 13-19, 22-25

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Species C: 22-25

Set III:

Species A: 1-4, 7-17, 20-57

Species B: 1-88

Set IV:

Species A: 1-8, 10-21, 23-43, 45-60, 62-77, 79-88

Species B: 1-29, 40-88

The following claim(s) are generic: 23-25.

7. The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: the **common technical feature** between **Groups I, II, III, IV, and V** is a helical member. This element cannot be a special technical feature under PCT Rule 13.2 because the element is shown in the prior art. Altman et al. (U.S. Patent No. 6,358,247) disclose a helical coil (102) in a surgical device that treats tissue. Therefore, this feature cannot be a special technical feature under PCT Rule 13.2 because it fails to provide contribution to the prior art.

8. A telephone call was made to Timothy Thomas on June 15, 2009 to request an oral election to the above restriction requirement, but did not result in an election being made.

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9. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

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- 10. The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.
- 11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 12. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

 All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.
- 13. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAYMI DELLA whose telephone number is (571)270-1429. The examiner can normally be reached on M-Th 7:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jackson can be reached on (571)272-4697. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. D./ Examiner, Art Unit 4137 June 15, 2009

/Gary Jackson/ Supervisory Patent Examiner Art Unit 4137